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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/147,237	04/20/1999	EIICHIRO YAGI	TOS-123-USA	1426

7590 03/05/2002

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EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 03/05/2002

34

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/147,237

Applicant(s)

YAGI ET AL.

Examiner

Francisco C Prats

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 2-10-02 and 2-27-02 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☒ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see attachment.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-4 and 15-17.

Claim(s) withdrawn from consideration: 5-14.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____.

Francisco C Prats
Primary Examiner
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ATTACHMENT TO ADVISORY ACTION

The responses filed February 11, 2002, and February 27, 2002, have been received and considered. The amendment of February 27, 2002, has not been entered because it raises new issues for search and consideration. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

The amendment of February 27, 2002, has not been entered because it raises new issues for search and consideration, because new claim 18 recites additional limitations which have not been searched or considered previously. While at first blush it appears that the antigen presentation effect recited in proposed new claim 18 would inherently result from any prior art application of glutathione to the skin, including the prior art of record, the new limitations in the claim simply have not been searched or considered with respect to the prior art, or § 112 issues. Therefore, non-entry of the amendment is clearly proper at this stage of prosecution.

As an aside, note that new claim 18 is improperly numbered, because claim 18 was originally presented in the amendment filed January 27, 2000. Thus, if new claim 18 were entered, the numbering of claims would not be in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be

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preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered new claim 18 should be renumbered as claim 21.

All of applicant's argument to date has been fully considered, and reconsidered, but is not persuasive of error. With regard to the suppression of antigen presentation by Langerhans' cells, argued as being unexpected by applicant, note specifically that the amendment at issue has not been entered, and new claim 18 not examined. Thus, it is not clear that the suppression of antigen presentation is in fact an unexpected result.

With respect to the arguments presented on February 11, 2002, the presence of the "consisting essentially of" language in the claims is again noted. However, MPEP § 2111.03 clearly states that claims recited in "consisting essentially of" language should be construed as if recited in "comprising" language, absent some evidence that the additional ingredients in the prior art process/product materially affect the basic and novel properties of the claimed invention:

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For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., *PPG [Industries v. Guardian Industries]*, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase 'consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See also *In re Janakirama-Rao*, 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963).

With regard to the presence of additional ingredients in N'Guyen's compositions, no part of the disclosure of the N'Guyen reference has been ignored. It is noted that N'Guyen includes glutathione in his solar cream for the disclosed purpose of being one of a group of stabilizing antioxidant agents. It is also noted that N'Guyen refers to the complementary action of the thiol and complexing agent as a "couple". However, the use of the term "couple" does not, as argued by applicant, mean that the glutathione and EDTA become covalently linked together or somehow complexed such that the glutathione becomes a different compound than the claimed glutathione. Nowhere does the reference suggest this. Applicant's argument is in error in this respect.

Moreover, as discussed in previous office actions, there is

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no evidence of record that any of the additional ingredients in the prior art composition affect the glutathione's ability to act to suppress immune function when the glutathione is applied to the skin. In fact, applicant's own examples demonstrate that numerous ingredients can be added to the glutathione without any material affect on glutathione's activity to suppress immune function. Such ingredients include EDTA, the precise ingredient asserted by applicant as rendering N'Guyen inapplicable as prior art. See specification at pages 22 and 23, Example 6, wherein "Ethylenediamine-tetraacetic acid trisodium dihydrate" (i.e. EDTA) is included in one of the exemplified formulations.

Applicant's own disclosure of an example comprising glutathione and EDTA supports the proposition that N'Guyen's solar cream composition "consists essentially of" glutathione, and that the presence of the additional ingredients in N'Guyen's composition does not affect the basic and novel properties of the composition as claimed. Moreover, applicant's own disclosure of an example comprising glutathione and EDTA undermines applicant's assertion that the combination of EDTA and glutathione somehow covalently bind or electrostatically complex such that the glutathione is converted to a different compound. The rejection must therefore be maintained.

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No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'F. Prats', is positioned above the printed name.

Francisco C Prats
Primary Examiner
Art Unit 1651

FCP
March 4, 2002